DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2771

WARNING LETTER

WL-CIN-8669-01
July 12, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Bruce A. Burgett, General Manager
The Carrollton Farmers Exchange
204 Second Street, N.W.
Carrollton, OH 44615

Dear Mr. Burgett:

A Food and Drug Administration (FDA) investigator conducted an inspection of your feed mill on 6/25/2001. The inspection found significant deviations from the requirements set forth in Title 21, Code of Federal Regulations, Part 589.2000 – Animal Proteins Prohibited in Ruminant Feed. This regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE).

Our inspection found your firm failed to label feeds that contain, or may contain, prohibited materials with the required cautionary statement **"Do not feed to Cattle or Other Ruminants"**. We suggest this statement be distinguished by different type size or color or other means of highlighting the statement so it is easily noticed by the purchaser.

There are no written procedures for cleaning out or flushing equipment after mixing feeds containing prohibited material. Additionally, you do not have records documenting that the system was cleaned or flushed in accordance with any written procedures.

You should establish adequate procedures and verify that the flush/clean-out method you use cleans out the remainder of preceding batches containing prohibited materials. Note: If you flush with feed ingredients, or sequence with non-ruminant feed, you must also label these products with the required cautionary statement "Do not feed to Cattle or Other Ruminants".

Your customer records are not sufficient to track the distribution of products that contain, or may contain, prohibited material

The deviations from regulations as noted above cause products being manufactured and distributed by your facility to be adulterated within the meaning of Section 402(a)(4) and misbranded within the meaning of Section 403(f) of the Federal Food, Drug, and Cosmetic Act (the Act).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. As a manufacturer of materials intended for animal feed use, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law. We have enclosed a copy of the FDA's Small Entity Compliance Guide to assist you with complying with the regulation. You should take prompt action to correct these violations, and you should establish a system whereby violations do not recur. Failure to promptly correct these violations may result in regulatory action, such as seizure and/or injunction, without further notice.

You should notify this office in writing within 15 working days of receipt of this letter, of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the violations, and prevent their recurrence. If corrective action cannot be completed in 15 days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Stephen J. Rabe, Compliance Officer, U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, Oh 45237, telephone (5 13) 679-2700 extension 167.

Sincerely,

Henry L. Fielden,
District Director

Enclosure: Small Entity Compliance Guide